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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 37/00 — A1

(11) International Publication Number: WO 98/08565

(43) International Publication Date: 5 March 1998 (05.03.98)

(21) International Application Number: PCT/US97/11051

(22) International Filing Date: 26 June 1997 (26.06.97)

(30) Priority Data:
08/705,334 29 August 1996 (29.08.96) US

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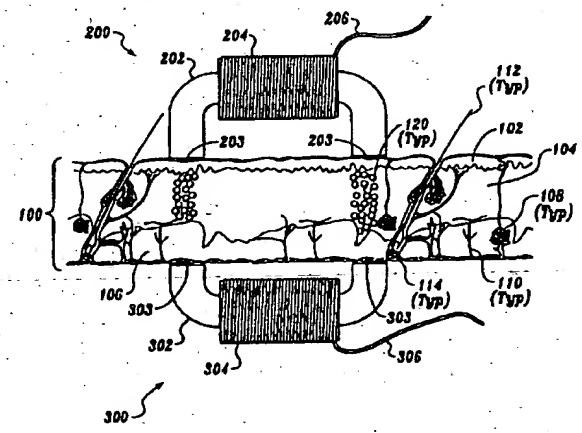
(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
With amended claims.

(54) Title: IMPROVED TRANSCUTANEOUS ELECTROMAGNETIC ENERGY TRANSFER



(57) Abstract

A method and apparatus for enhancing transcutaneous energy transfer to provide power to a medical device that is disposed within the body of a patient. A magnetic field is created by an external transmitting coil (200), which induces an electrical current in a receiving coil (300) that has been placed under the patient's skin (100). The flux path magnetic permeability between the receiving and transmitting coils is enhanced by the implantation of particles (120) into dermis (104) within the skin at that site. The particles, which comprise soft iron or other material having a characteristic high magnetic permeability, are preferably implanted using either a hypodermic needle (150) or a medical air injection device (160). A biocompatible material such as Teflon™ is applied as a coating (123) to the particles. To implant the particles, they are preferably first suspended in a liquid, forming a mixture that is readily delivered to the desired location. The particles are dispersed in a deposit below the epidermis, so that the deposit is between pole faces of the transmitting and the receiving coils. The efficiency of transcutaneous power transfer increases because the magnetic flux density coupling the transmitting and receiving coils is improved by the particles.

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IMPROVED TRANSCUTANEOUS ELECTROMAGNETIC ENERGY TRANSFER

Field of the Invention

This invention generally relates to the transfer of electromagnetic energy between a source coil and a receiver coil, and more specifically, to a method and system for improving the efficiency with which electromagnetic power is transcutaneously transferred to energize a medical device implanted within a patient's body.

Background of the Invention

Various types of medical devices such as cochlear implants, artificial hearts, and neural stimulators have been developed that are designed to be surgically inserted within a patient's body to carry out a medically related function for an extended period of time. Although a power lead connected to the implanted device and extending outside the patient's body can be used to supply electrical power required to energize the device, any lead that passes through the skin increases the risk of infection if left in place for more than a few days. Thus, power can be supplied to an implanted medical device from an internal battery pack to avoid this problem. However, any battery used for extended periods of time will eventually need to either be recharged or replaced. Replacing an internally implanted battery subjects the patient to further invasive surgery and is thus not desirable.

An alternative solution to this problem provides for recharging the battery by transcutaneously coupling power from an external source to an implanted receiver that is connected to the battery. Although power can be coupled from an external source at radio frequencies using matching antennas, it is generally more efficient to employ an external transmitter coil and an internal receiving coil that are inductively electromagnetically coupled to transfer power at lower frequencies. In this approach, the external transmitter coil is energized with

alternating current (AC), producing a varying magnetic flux that passes through the patient's skin and excites a corresponding AC current in the internal receiving coil. The current in the receiving coil is then typically rectified and filtered for use in charging a battery pack that provides power to the implanted device, but may also be directly applied for powering the implanted device. It should be noted that the receiving coil and any related electronic circuitry may be located at a different point in the patient's body from that at which the implanted device is disposed.

The efficiency with which electromagnetic power is transcutaneously transferred between two coils is a function of the distance between the coils, the design of the coils, including the type of core used for each, the size of the core of each coil, the number of turns of electrical conductor used for each coil, the current flowing through the transmitting coil, and other factors. Air has a relatively poor magnetic permeability characteristic of $m = 4p \times 10^{-7}$ Henry/meter, and the magnetic permeability of the dermal layer separating an internal receiving coil from an external transmitting coil is only slightly better. By comparison, the magnetic permeability characteristic of iron is approximately $m = 100$ to 600 Henry/meter. The variation in the magnetic permeability of iron is inversely proportional to the density of the magnetic flux. Thus, transcutaneous electromagnetic power transfer between two coils is relatively inefficient compared to the efficiency that could be achieved if the two coils were coupled by a material such as iron, having a superior magnetic permeability.

Clearly, it is desirable to limit the amount of time required for inductively coupling electrical power to charge an internal battery supply used to energize an implanted device. Similarly, it would be desirable to improve the efficiency with which power is coupled to an implanted device that is directly energized by transcutaneously transferred power. The time required to charge a battery pack is generally proportional to the efficiency of the inductive coupling process. In addition, due to miniaturization of the receiving coil used in certain types of implanted devices, it is very important to optimize the inductive coupling between the external transmitter coil and the receiving coil connected to the internal device, particularly when the device is directly energized. Design changes in the transmitter and receiver coils are likely only to achieve a minimal improvement in the efficiency of the power transfer process. Further enhancements to the efficiency of the process will require a different approach.

Summary of the Invention

The present invention is directed to a method for enhancing transcutaneous energy transfer that is used to provide electrical power to a medical device implanted within a patient's body. Transcutaneous energy transfer employs a transmitting coil that is disposed externally, generally in contact with a patient's skin and positioned directly over or opposite a receiving coil that has been implanted within the patient's body. The external transmitting coil produces a magnetic field that induces a current in the internal receiving coil, which is used to supply energy for the implanted medical device.

The magnetic permeability of tissue is low, so that the coupling between the external transmitting coil and the internal receiving coil is relatively poor. The present invention addresses this problem by improving the coupling between the transmitting and receiving coils. In the invention, a plurality of particles having a characteristic relatively high magnetic permeability are implanted in the patient's body, above the internal receiving coil and under the top surface of the patient's skin. These particles improve the transfer of electromagnetic energy by enhancing the magnetic permeability of the flux path between the transmitting and receiving coils.

Materials such as soft iron, permalloy, mu metal alloy, and supermalloy comprise a core of each of the particles, and the core is coated with a protective biocompatible layer. This layer can be manufactured in various colors to selectively cosmetically mask the particles, minimizing their visibility through the skin, or alternatively, to enhance the visibility of the particles, making it easier to locate the internal receiving coil that lies under the particles. Each particle has a size within the range from about 50 micrometers to about one millimeter.

A further aspect of the present invention is directed to a method for implanting a plurality of such particles at a site within the patient's body. Preferably, the particles are added to a liquid so that they are suspended, forming a mixture. The mixture is then injected into the patient's body, using a hypodermic needle or an air injection gun. Alternatively, a plurality of small incisions may be made in the patient's skin and the particles implanted in the incisions.

Brief Description of the Drawing Figures

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 is a cross-sectional view of one of the particles of the present invention, showing a biocompatible coating around a core;

FIGURE 2 is a side section view of skin containing implanted particles having a relatively high magnetic permeability in accord with the present invention and illustrating a transmitter coil and a receiving coil that couple power transcutaneously through a path comprising the particles;

FIGURE 3 is a side sectional view of skin showing a hypodermic needle inserted into the skin and showing the deposition of the particles in the dermis as the needle is withdrawn;

FIGURE 4 is a side sectional view of the skin showing the needle further withdrawn (compare to FIGURE 3) as the particles are injected;

FIGURE 5 is a side sectional view of the skin with a needle positioned above the top surface of the skin and showing the particles deposited within the skin;

FIGURE 6 is a side sectional view of the skin with a medical air injection nozzle positioned against the top surface of the skin and showing the result of having uniformly deposited magnetically permeable particles within the skin by air injection;

FIGURE 7 is a side sectional view of the skin, showing a heavy deposit of particles within the skin;

FIGURE 8 is a side sectional view of the skin, showing a light deposit of the particles within the skin; and

FIGURE 9 is a side sectional view of the skin, showing a columnar deposit of the particles within the skin.

Description of the Preferred Embodiment

A first embodiment of a technique to improve transcutaneous energy transfer to a medical device (not shown) that has been implanted within a patient's body is illustrated in FIGURE 2. The human body is protected by a layer of skin 100, generally comprising a top layer or epidermis 102, and a bottom layer or dermis 104. The skin is part of a very complex group of organs collectively referred to as the integumentary system. Also included within this system are hair follicles 114, sweat glands 108, and capillary blood vessels 110. The skin borders an internal layer of subcutaneous tissue or hypodermis 106. Hypodermis 106 anchors skin 100 to the underlying structure of the body, yet allows the skin to move relative to the body.

Although the magnetic permeability of the integumentary system is slightly better than air, it is still relatively poor, which substantially limits the efficiency with which electromagnetic power can be transferred transcutaneously. It will be recalled from the discussion in the Background of the Invention that transcutaneous energy transfer provides means for coupling power from an external source to an internally disposed medical device that has been surgically implanted within the body of a patient. The present invention greatly improves the efficiency with which power is transmitted transcutaneously for this purpose.

As illustrated in FIGURE 2, an external transmitting coil 200 is illustrated in contact with epidermis 102, generally opposite a receiving coil 300, which has been surgically or endoscopically implanted below hypodermis 106. Transmitting coil 200 comprises a winding 204, a core 202, and wire leads 206. Wire leads 206 are connected to an external power supply that provides an AC voltage, forcing a substantial current to flow through winding 204, so that a corresponding AC magnetic field is produced by transmitting coil 200. It will be apparent that winding 204 could also be energized with a pulsating DC voltage.

Receiving coil 300 comprises a winding 304, a core 302, and wire leads 306. Wire leads 306 are used to transfer current induced in winding 304 to the remotely disposed medical device that is implanted within the patient's body. The current induced in winding 304 can be used directly to power the device or can be rectified and applied to charging a battery that normally provides power to the implanted device. Details of the medical device circuitry are not illustrated in the drawings nor described in this disclosure, since such details are irrelevant to the present invention.

The transmitting coil has a winding wrapped around a generally U-shaped core. The receiving coil similarly includes a winding wrapped around a generally U-shaped core. The windings are wrapped around each core in concentric layers (not separately shown). The magnetic flux density within core 202 of transmitting coil 200 is dependent upon the magnetic permeability characteristics of transmitting core 202, the number of turns of conductor comprising winding 204, and the magnitude of the current flowing through winding 204. The materials comprising core 202 and core 302 are selected because of their characteristic high magnetic permeability to optimize the magnetic flux density within the cores. Core 202 directs and focuses the magnetic flux from winding 204 out through pole faces 203, which are disposed at opposite ends of the core. On receiving coil 300, opposite ends of core 302 comprise pole faces 303 that receive the

magnetic flux produced by transmitting coil 200 and direct the flux through the core of receiving coil 300. The magnetic flux within core 302 causes an electrical current to be induced in winding 304 that is proportional to the intensity of the magnetic flux within the core, and to the number of turns of the conductor comprising winding 304. However, the amount of power transferred to receiving coil 300 to produce the flux within core 302 is directly proportional to the magnetic permeability of the material ***between*** pole faces 203 and 303.

Power transfer between the transmitting coil and the receiving coil can be improved in two ways. First, the magnitude of the magnetic flux produced by the transmitting coil can be increased, e.g., by increasing the current flowing in the windings of the transmitting coil. However, a higher current requires physically larger windings, i.e., more turns of the conductor comprising the winding, and may require a larger gauge conductor to safely carry the higher current. There is a practical limit to the size of the transmitting coil used for this purpose. A second way to improve power transfer is to increase flux density coupling between the facing pole faces of the transmitting and receiving coils. The flux density can be increased by increasing the magnetic permeability of the material comprising the physical barrier separating the pole faces of the transmitting coil from the pole faces of the receiving coil. The second technique increases the efficiency of power transfer without requiring any modification of the transmitting and receiving coils or any changes in the power supply or current that energizes transmitting coil 200. The present invention is thus directed to increasing the magnetic permeability of the tissue separating transmitting coil 200 and receiving coil 300 to improve the efficiency with which electromagnetic energy is transferred between the two coils.

To improve the magnetic permeability of skin or other tissue disposed between the transmitting and receiving coils, magnetically permeable particles 120 are implanted within the tissue of a patient's body at that site so that the particles lie between the pole faces of the two coils. To facilitate their implantation at the site, particles 120 are preferably added to a saline solution or other biocompatible liquid to form a mixture in which the particles are at least initially suspended. The mixture is then drawn into a delivery device and the delivery device is positioned on the top surface of skin 100, at the site overlying receiving coil 300. Using the delivery device, the mixture is forced into dermis 104 at the site. These steps are repeated as necessary to achieve a desired

density of particles 120 beneath epidermis 102, and create a generally uniform distribution of the particles, at least overlying pole faces 303 of receiving coil 300.

In FIGURE 3, a hypodermic needle 150 is illustrated as the delivery device used to implant particles 120 at the site. Hypodermic needle 150 is shown after it has been inserted through epidermis 102 and into dermis 104. The tip of the needle rests just above hypodermis 106 and the particles are being injected through the needle as it is withdrawn from the dermis. In FIGURE 4, hypodermic needle 150 is shown partially withdrawn from dermis 104, leaving behind a columnar deposit of particles 120. These particles are deposited within the column at a substantially uniform density. The implanted particles have a characteristic magnetic permeability that is substantially greater than skin and thus greatly improves the efficiency of transcutaneous electromagnetic power transfer between the transmitting coil and receiving coil.

As shown in FIGURE 1, each particle 120 comprises a core 121 of a material such as soft iron, permalloy, mu metal alloy, or supermalloy having a characteristic high magnetic permeability. A coating 123 of a biocompatible material such as one of the polyurethane or TEFLON™ compounds typically used for coating medical implants is applied to the particle core. Particles 120 are substantially spherical, and can have a diameter from about 50 micrometers to about 1 millimeter. Since epidermis 102 is relatively translucent, particles 120 may discolor the skin at the site of their implantation, possibly causing it to appear a mottled gray color. However, by coloring coating 123 various appropriate flesh colors, particles 120 may be made to cosmetically blend with the skin of the patient. This option is further discussed below.

Referring now to FIGURE 5, hypodermic needle 150 is illustrated positioned above epidermis 102 after it has been used to implant multiple columnar deposits of particles 120 within dermis 104. The resulting multiple columnar deposits of particles implanted beneath epidermis 102 are generally analogous to the dye pigment deposits introduced into the dermis when creating a tattoo. A tattoo artist employs a needle to inject multiple colored pigment clusters, having diameters of approximately 140 to 180 micrometers, beneath the top surface of the skin. The deposits of dye pigment define the tattoo. Similarly, in the present invention, a particular area of skin located above a receiving coil is injected with multiple deposits of particles 120, and the particles are generally analogous to the colored pigment clusters of a tattoo. However, epidermis 102 is relatively translucent and a patient treated with the present invention may prefer

that the introduction of particles 120 not change the appearance of the skin. In other cases, it may be preferable that the implanted particles be clearly visible to facilitate accurately positioning transmitting coil 200 against epidermis 102, immediately opposite receiving coil 300. Thus, the color of coating 123 on particles 120 may be selected to either enhance or reduce the extent to which the particles are visible through epidermis 102.

An alternative method for implanting particles 120 is illustrated in FIGURE 6. In this Figure, a medical air injection nozzle 160 having an injection channel 162 is shown positioned above a columnar deposit of particles 120 that have been injected into the dermis using the device. The air injection nozzle employs pressurized air to force a plurality of particles 120 through epidermis 102, producing a columnar deposit of particles 120 within dermis 104. One advantage of the air injection nozzle method for implanting the particles is the capacity of this device to deliver a generally uniform density of implanted particles with each injection. In contrast, the columnar deposit density can vary between columns when a hypodermic needle is employed to implant particles 120. The density of the particles injected using a hypodermic needle is dependent upon the pressure applied by a particular individual against a plunger of the syringe (not shown) and the rate at which the needle is withdrawn as the injection is delivered, both of which can vary.

Particles 120 can be implanted within tissue in various selected densities. For example, referring to FIGURE 7, a uniform high density deposit of particles 120 is shown implanted beneath epidermis 102. In FIGURE 8, a uniform light density deposit of particles 120 is shown, and in FIGURE 9, multiple columnar high density deposits of particles 120 are illustrated. Typically, a medical practitioner would select an appropriate density deposit of particles 120 for use with a specific patient, to provide a required magnetic flux density for the transfer of electromagnetic energy from transmitting coil 200 to receiving coil 300. Various parameters that may determine the density of the particles used with a specific patient include the power requirement of the medical device being energized, the thickness of skin 100 at the site selected, the size of the implanted receiver coil, the electrical current supplied to the transmitting coil, the size of the transmitting coil, (i.e., the number of turns of conductor used for winding 204), and the distribution of the flux pattern.

As an alternative to injecting the particles using a needle or air injection nozzle, as described above, it is also contemplated that a plurality of small

incisions can be made through epidermis 102 and into dermis 104 at the site overlying receiving coil 300. The particles can then be implanted within the pockets formed by the incisions, using a small catheter or other appropriate tools, leaving a columnar deposit of the particles at each small incision.

It is also contemplated that the present invention can be employed in connection with the implantation of particles within bones and/or tissue at other sites within the body to improve the magnetic permeability, which couples a transmitting coil and receiving coil and the power transferred between the two coils. To reach implantation sites deep within a patient's body, a longer hypodermic needle could be employed or the site could be surgically exposed to facilitate the injection of the particles using an air injection nozzle or needle.

Although the present invention has been described in connection with several preferred forms of practicing it, those of ordinary skill in the art will understand that many other modifications can be made thereto within the scope of the claims that follow. Accordingly, it is not intended that the scope of the invention in any way be limited by the above description, but instead be determined entirely by reference to the claims that follow.

The invention in which an exclusive right is claimed is defined by the following:

1. A method for enhancing transcutaneous energy transfer within a body, comprising the steps of:

(a) providing a plurality of particles comprising a material having a characteristic magnetic permeability substantially greater than that of tissue in the body; and

(b) implanting the plurality of particles at a site within the tissue of the body so that the plurality of particles are dispersed in a spaced-apart array, said plurality of particles comprising an enhanced flux path for transferring electromagnetic energy through the tissue at said site.

2. The method of Claim 1, further comprising the step of applying a biocompatible coating to each of the plurality of particles.

3. The method of Claim 2, wherein the step of coating includes the step of coloring the coating to either make the coating more or less visible relative to a patient's skin color.

4. The method of Claim 1, wherein the step of implanting includes the step of mixing the plurality of particles into a liquid to form a mixture.

5. The method of Claim 4, further comprising the step of injecting the mixture into the tissue at said site.

6. The method of Claim 4, further comprising the step of injecting the mixture into the tissue at said site using an air gun.

7. The method of Claim 4, further comprising the step of injecting the mixture into the tissue at said site using a needle.

8. The method of Claim 1, further comprising the step of making a plurality of incisions in the tissue adjacent to the site and implanting the plurality of particles in the plurality of incisions.

9. The method of Claim 1, wherein each of the plurality of particles has a size within the range from about 50 micrometers to about one millimeter.

10. The method of Claim 1, wherein the plurality of particles are implanted within the tissue in a plurality of spaced-apart columns.

11. Apparatus for enhancing transcutaneous energy transfer within a body, comprising:

(a) a plurality of particles comprising a material having a characteristic magnetic permeability substantially greater than that of tissue in the body; and

(b) means for implanting the plurality of particles at a site within the tissue of the body so that the plurality of particles are dispersed in a spaced-apart array, said plurality of particles comprising an enhanced flux path for transferring electromagnetic energy through the tissue at said site.

12. The apparatus of Claim 11, wherein the plurality of particles are each coated with a layer of a biocompatible material.

13. The apparatus of Claim 12, wherein the layer of the biocompatible material is selectively colored to make the particles either more or less visible relative to a patient's skin.

14. The apparatus of Claim 11, wherein the plurality of particles are mixed into a liquid to form a mixture prior to being implanted in the tissue at the site.

15. The apparatus of Claim 14, wherein the means for implanting the plurality of particles comprise an air gun that is employed to inject the plurality of particles within the mixture into the tissue at the site.

16. The apparatus of Claim 14, wherein the means for implanting the plurality of particles comprise a needle that is employed to inject the plurality of particles within the mixture into the tissue at the site.

17. The apparatus of Claim 11, wherein each of the plurality of particles has a size within the range from about 50 micrometers to about one millimeter.

18. The apparatus of Claim 11, wherein the plurality of particles are implanted in generally uniform density deposits, having a density selected to achieve a required magnetic permeability.

19. The apparatus of Claim 11, wherein the material comprising the plurality of particles is selected from the group consisting of soft iron, permalloy, mu metal alloy, and supermalloy.

AMENDED CLAIMS

[received by the International Bureau on 1 September 1997 (01.09.97); original claims 1-3, 5-7 and 10-19 amended; new claims 20-22 added; remaining claims unchanged (3 pages)]

The invention in which an exclusive right is claimed is defined by the following:

1. A method for enhancing transcutaneous energy transfer from an external source to a receiver implanted within a body to energize a medical device disposed within the body, comprising the steps of:

(a) providing a plurality of particles comprising a material having a characteristic magnetic permeability substantially greater than that of tissue in the body; and

(b) implanting the plurality of particles at a site within the tissue of the body so that the plurality of particles are dispersed in a spaced-apart array, said plurality of particles comprising an enhanced flux path between the external source and the receiver for transferring electromagnetic energy through the tissue at said site and thereby adapted to energize the medical device.

2. The method of Claim 1, wherein each of the plurality of particles further comprises a biocompatible coating.

3. The method of Claim 2, wherein the biocompatible coating is colored to either make the biocompatible coating more or less visible relative to a patient's skin color.

4. The method of Claim 1, wherein the step of implanting includes the step of mixing the plurality of particles into a liquid to form a mixture.

5. The method of Claim 4, wherein the step of implanting further comprises the step of injecting the mixture into the tissue at said site.

6. The method of Claim 4, wherein the step of implanting further comprises the step of injecting the mixture into the tissue at said site using an air gun.

7. The method of Claim 4, wherein the step of implanting further comprises the step of injecting the mixture into the tissue at said site using a needle.

8. The method of Claim 1, further comprising the step of making a plurality of incisions in the tissue adjacent to the site and implanting the plurality of particles in the plurality of incisions.

9. The method of Claim 1, wherein each of the plurality of particles has a size within the range from about 50 micrometers to about one millimeter.

10. The method of Claim 1, wherein the step of implanting further comprises the step of disposing the plurality of particles within the tissue in a plurality of spaced-apart columns.

11. A kit having components capable of being used together for enhancing transcutaneous energy transfer between an external energy source and a receiver implanted within a body to energize a medical device disposed within the body, comprising:

(a) a plurality of particles comprising a material having a characteristic magnetic permeability substantially greater than that of tissue in the body and adapted to be implanted within the body; and

(b) means adapted for implanting the plurality of particles at a site within the tissue of the body so that the plurality of particles are dispersed in a spaced-apart array, said plurality of particles, when implanted by said means, comprising an enhanced flux path for transferring electromagnetic energy through the tissue at said site to energize the medical device.

12. The kit of Claim 11, wherein the plurality of particles are each coated with a layer of a biocompatible material.

13. The kit of Claim 12, wherein the layer of the biocompatible material is selectively colored to make the particles either more or less visible relative to a patient's skin.

14. The kit of Claim 11, wherein the plurality of particles are adapted to be mixed into a liquid to form a mixture prior to being implanted in the tissue at the site.

15. The kit of Claim 14, wherein the means for implanting the plurality of particles comprise an air gun that is adapted to inject the plurality of particles within the mixture into the tissue at the site.

16. The kit of Claim 14, wherein the means for implanting the plurality of particles comprise a needle that is adapted to inject the plurality of particles within the mixture into the tissue at the site.

17. The kit of Claim 11, wherein each of the plurality of particles has a size within the range from about 50 micrometers to about one millimeter.

18. The apparatus of Claim 11, wherein the means for implanting and the plurality of particles are adapted to implant the plurality of particles in generally uniform density deposits, having a density selected to achieve a required magnetic permeability.

19. The kit of Claim 11, wherein the material comprising the plurality of particles is selected from the group consisting of soft iron, permalloy, mu metal alloy, and supermalloy.

20. A method for enhancing transcutaneous energy transfer within a body, comprising the steps of:

(a) providing a plurality of particles comprising a material having a characteristic magnetic permeability substantially greater than that of tissue in the body, said plurality of particles each including a biocompatible coating; and

(b) implanting the plurality of particles at a site within the tissue of the body so that the plurality of particles are dispersed in a spaced-apart array, said plurality of particles comprising an enhanced flux path for transferring electromagnetic energy through the tissue at said site.

21. A method for enhancing transcutaneous energy transfer within a body, comprising the steps of:

(a) providing a plurality of particles comprising a material having a characteristic magnetic permeability substantially greater than that of tissue in the body, each of said plurality of particles including a biocompatible coating that is colored to either make the biocompatible coating more or less visible relative to a patient's skin color; and

(b) implanting the plurality of particles at a site within the tissue of the body so that the plurality of particles are dispersed in a spaced-apart array, said plurality of particles comprising an enhanced flux path for transferring electromagnetic energy through the tissue at said site.

22. A method for enhancing transcutaneous energy transfer within a body, comprising the steps of:

(a) providing a plurality of particles comprising a material having a characteristic magnetic permeability substantially greater than that of tissue in the body; and

(b) implanting the plurality of particles at a site within the tissue of the body so that the plurality of particles are dispersed in a spaced-apart array comprising a plurality of spaced-apart columns, said plurality of spaced-apart columns comprising an enhanced flux path for transferring electromagnetic energy through the tissue at said site.

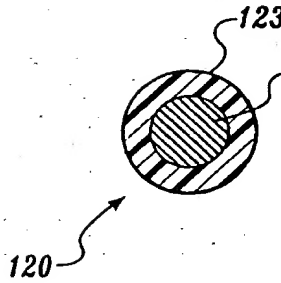
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Fig. 1

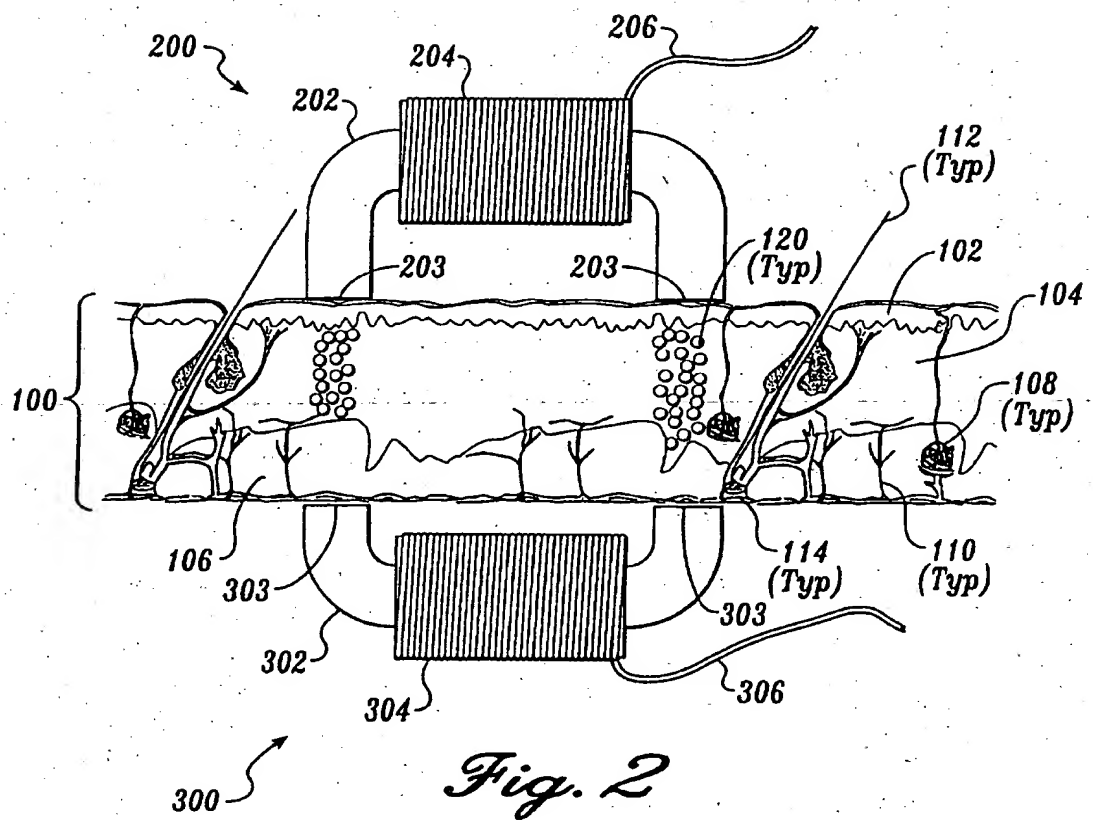
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Fig. 2

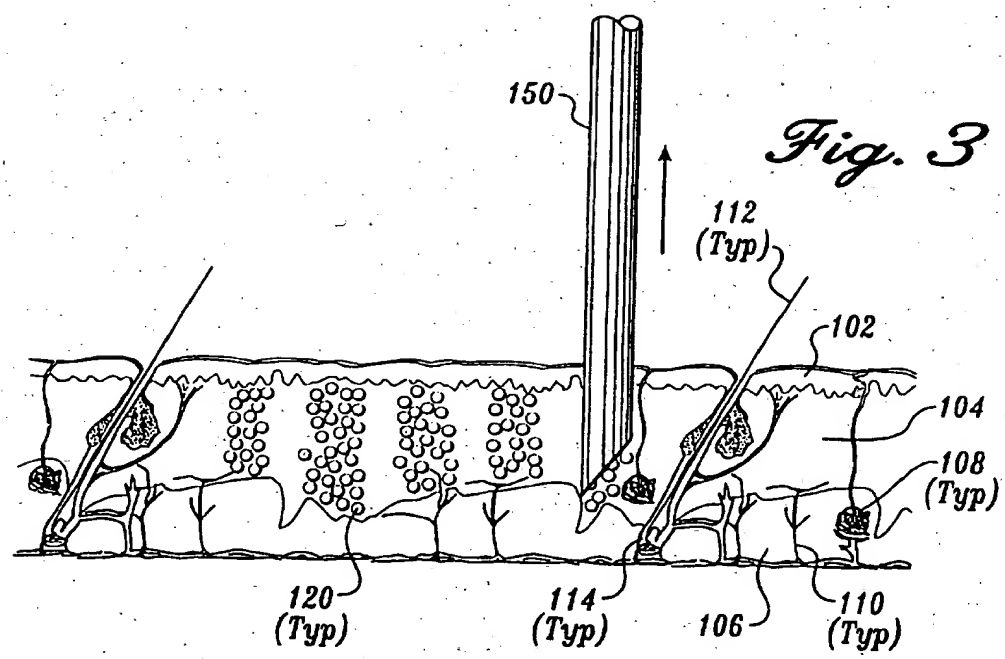
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Fig. 3

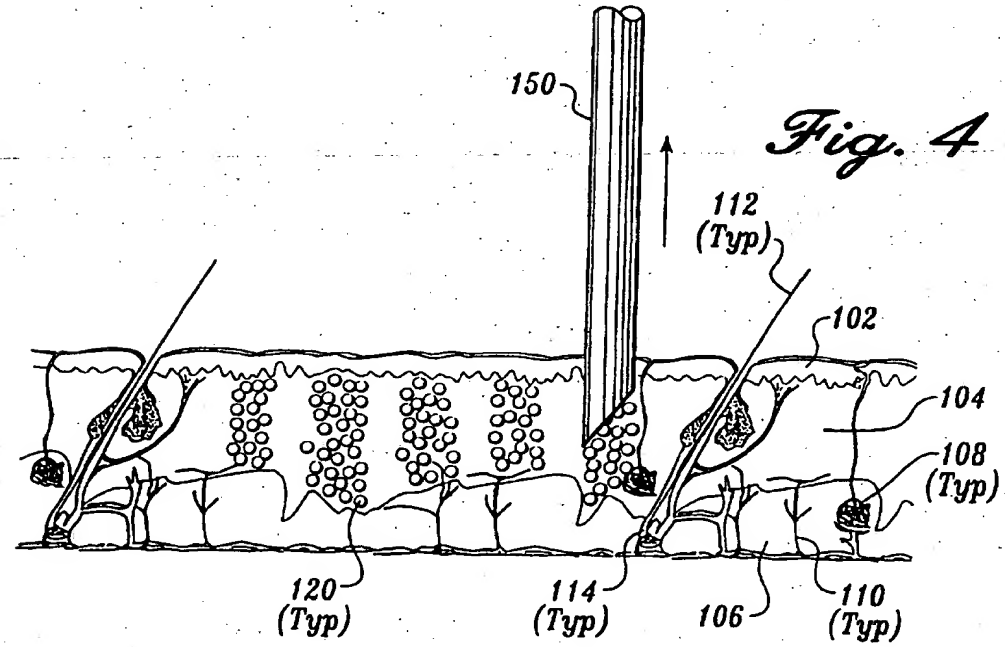
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Fig. 4

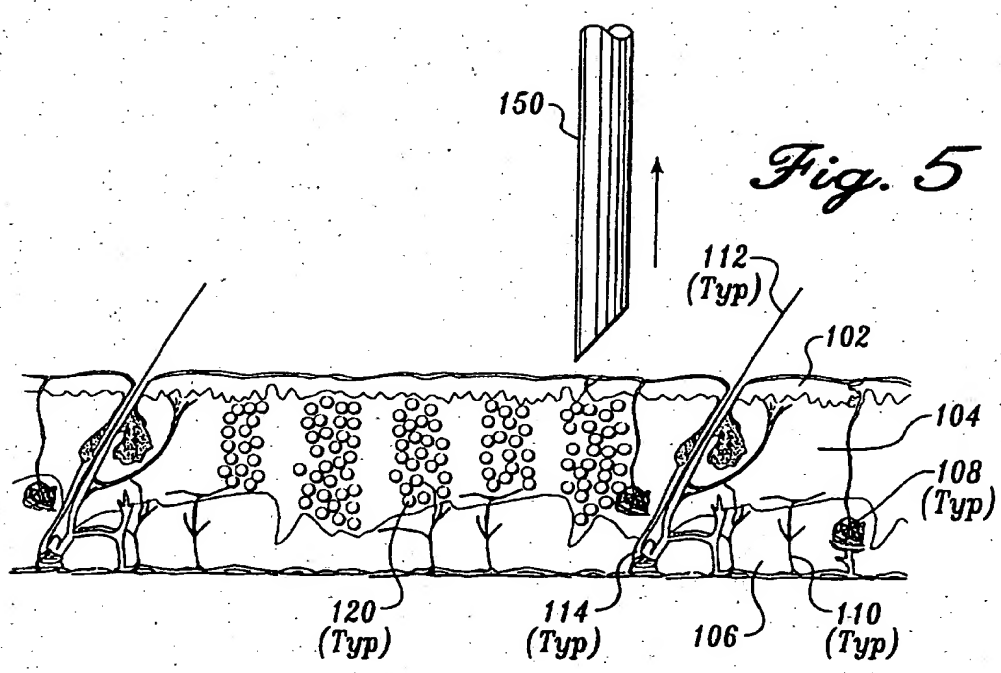
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Fig. 5

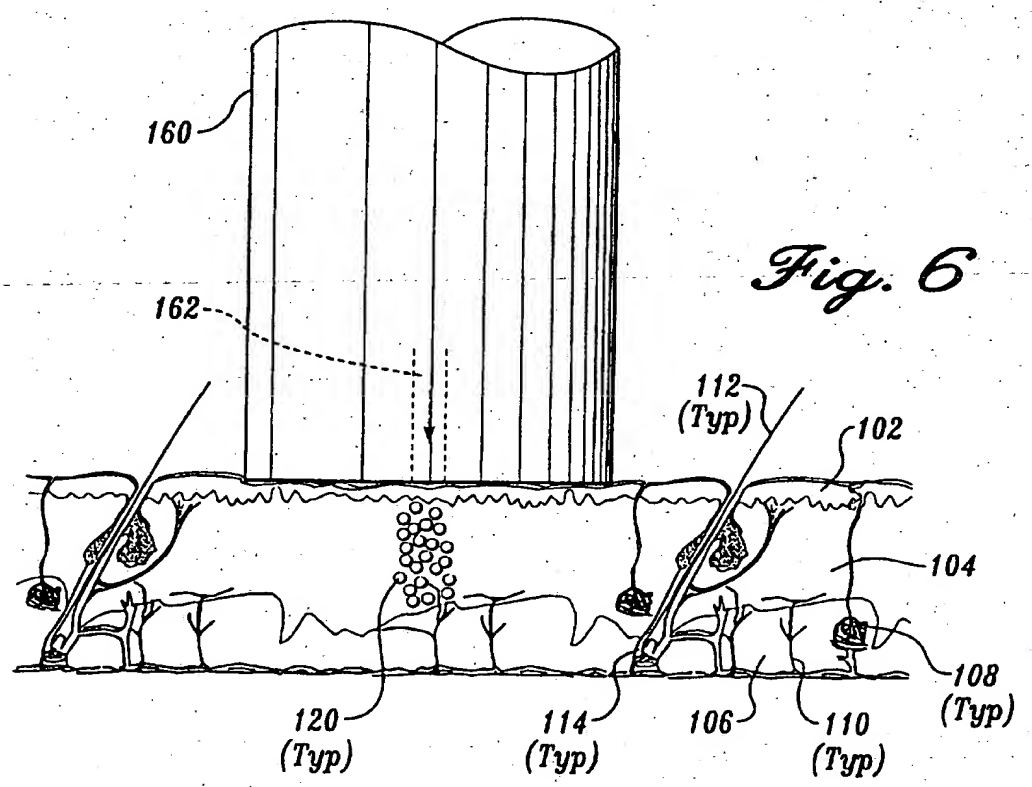
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Fig. 6

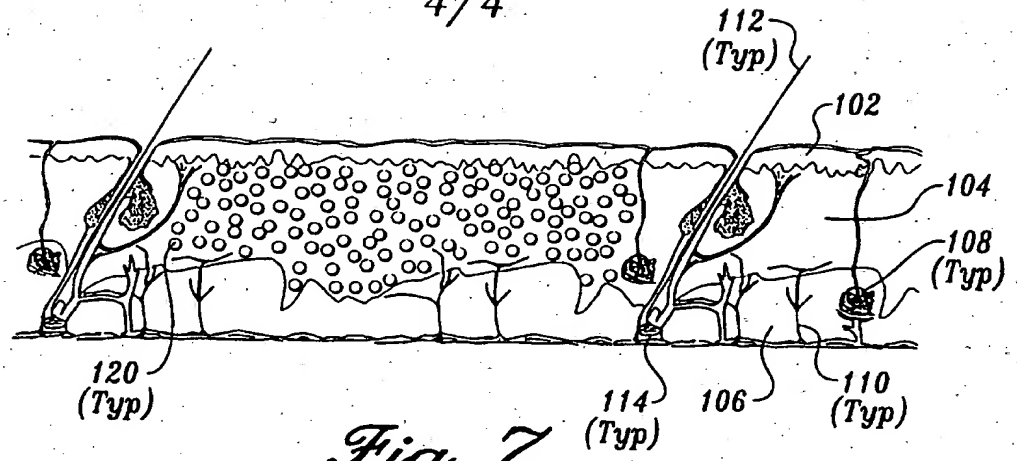

Fig. 7

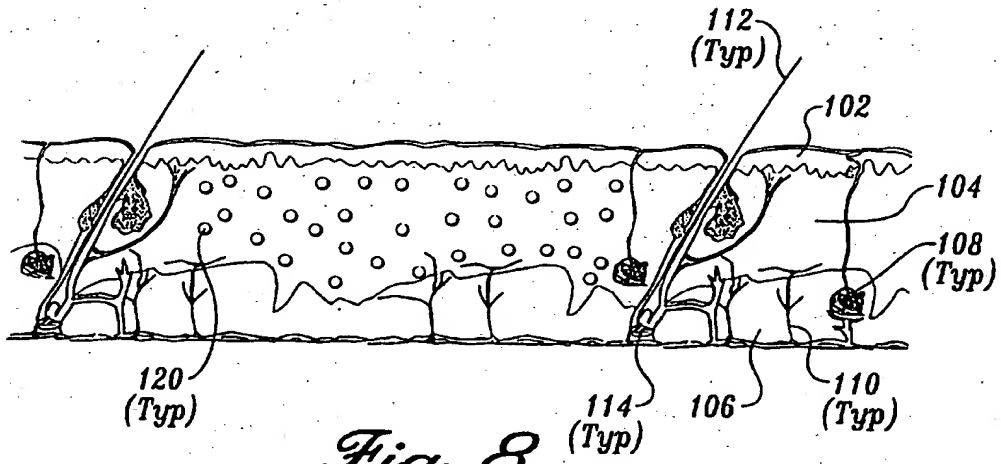

Fig. 8

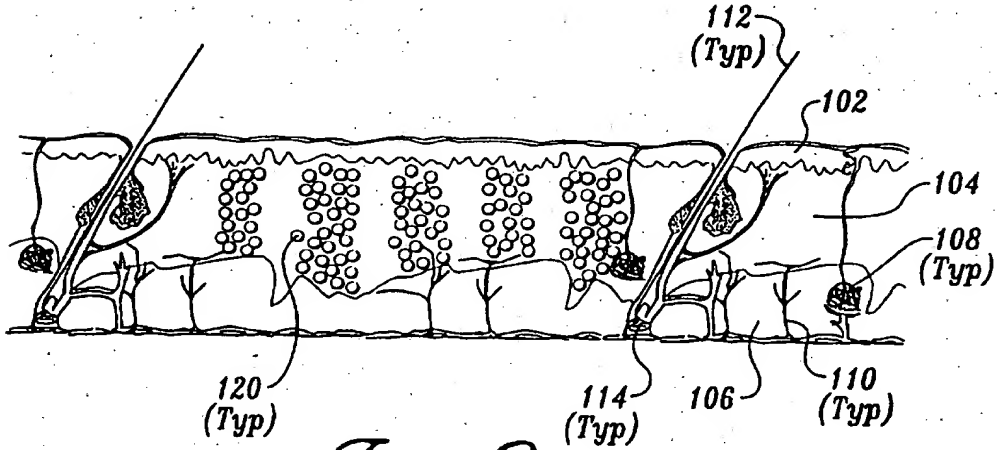

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/11051

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 37/00
US CL :600/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/897-899; 600/3, 12, 13; 607/33, 34, 61

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,067,952 A (GUDOV et al) 26 November 1991, entire document.	1, 4, 5, 9, 11, 14, 17 --- 6-8, 15, 16
X --- Y	US 4,829,984 A (GORDON) 16 May 1989, entire document.	1, 4, 5, 11, 14, 18, 19 --- 6-8, 15, 16
X --- Y	US 5,262,176 A (PALMACCI et al) 16 November 1993, entire document.	11, 12, 14, 19 --- 13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 5/00 | A1

(11) International Publication Number: WO 98/06456

(43) International Publication Date: 19 February 1998 (19.02.98)

(21) International Application Number: PCT/US97/11052

(22) International Filing Date: 26 June 1997 (26.06.97)

(30) Priority Data:
08/702,252 8 August 1996 (08.08.96) US

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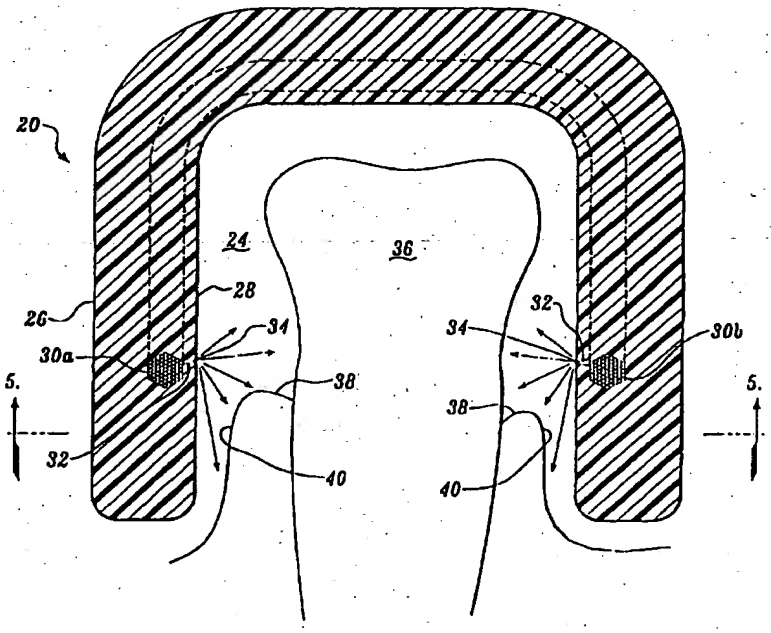
(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
With amended claims.

(54) Title: METHOD AND APPARATUS TO TREAT GINGIVAL AND PERIODONTAL DISEASE

(57) Abstract

Method and apparatus employing light therapy to destroy organisms causing oral diseases. A fixture (20) is formed in a U shape and having a trough or cavity (24) with a generally inverted U-shaped cross section open along a lower surface. Light is emitted from spaced-apart points disposed adjacent to inner walls (28) of the fixture so that the light is incident upon a gum line of a patient. A photoreactive agent is applied to the gum line of the patient prior to initiating administration of the light therapy. Since the light has substantially the same range of wavelengths or waveband as an absorption waveband of the photoreactive agent, disease-causing organisms that exist along the gum line and which preferentially absorb the photoreactive agent are destroyed by the light administered using the fixture. An external light source can be employed by using a bundle (30a, 30b) of optical fibers (32) to convey the light from outside the oral cavity to spaced-apart points along the inner wall of the fixture at which ends (34) of individual cleaved optical fibers are directed toward the gum line. Alternatively, a plurality of spaced-apart light emitting devices (52/62) can be mounted adjacent the inner walls of the fixture so that the light the devices emit is directed along the gum line. Since the light intensity of these various types of light sources is relatively low, the duration of the PDT is likely to range from minutes to hours.



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METHOD AND APPARATUS TO TREAT GINGIVAL AND PERIODONTAL DISEASE

Field of the Invention

This invention generally relates to a method and apparatus for treating diseases of the oral cavity, and more specifically, to the use of photodynamic therapy (PDT) for treatment of gingival and periodontal diseases and for destroying organisms that cause caries.

Background of the Invention

The field of dentistry has undergone significant changes due to improvements in personal hygiene products, improvements in dental care technology, and greater awareness by the public of appropriate preventive measures to avoid dental disease and loss of teeth. However, many dental problems resulting in the extraction of teeth are still caused by periodontal and gingival diseases of the tissue supporting the teeth, in some cases because of a refusal to floss and apply other personal hygiene habits that will minimize the formation of plaque. While antibiotic therapy is sometimes useful in destroying the organisms that cause periodontal and gingival diseases, in many cases, the diseases advance to the point at which teeth must be extracted.

As an alternative to antibiotics, the use of photosensitizers in connection with relatively lower power laser light sources for treating oral pathogens *in vitro* is disclosed in several papers, including: "Sensitization of Oral Bacteria to Killing by Low-Power Laser Radiation," by Michael Wilson, John Dobson, and Wilson Harvery, pp. 77-81, Current Microbiology, Vol. 25 (1992); "Lethal Photosensitization of Bacteria in Subgingival Plaque from Patients with Chronic Periodontitis," by S. Sarkar and M. Wilson, pp. 204-210, Journal of Periodontal Research, Vol. 28 (1993); and "Sensitization of Periodontopathogenic Bacteria to Killing by Light from a Low-Power Laser," by M. Wilson, J. Dobson, and S.

Sarkar, pp. 182-187, Oral Microbiology and Immunology, Vol. 8 (1993). Each of these papers describes how a low power He/Ne gas laser having an output of about 7.3 mW was used to destroy cultivated colonies of oral pathogens (*ex vivo*) that had been sensitized with various photoreactive agents. Laser light was administered to the photosensitized bacterial colonies for short periods of time to achieve substantial reduction in the viable organisms in such colonies. In "Targetable Photoactivatable Drugs - Synthesis of Water-Soluble Galactosamine Containing Polymeric Carriers of Chlorin e_6 and Their Photodynamic Effect on PLC Cells *in vitro*," by Krinik et al., pp. 70-83, SPIE Vol. 997 Advances in Photochemotherapy (1988), it is demonstrated that tumor cells can be destroyed with a low irradiance light source (i.e., 0.77 mW/cm^2) if the period of irradiance is sufficient long (i.e., up to 24 hours). It is possible that other low power light sources such as LEDs can be employed for administering PDT to treat pathogenic gingival and periodontal organisms if the low level light is applied for time periods of thirty minutes or longer.

Several different embodiments of light emitting probes designed to be transcutaneously introduced into the body of a patient and disposed at a desired treatment site to administer PDT using low light level sources for extended periods of time are taught in commonly assigned U.S. Patent No. 5,445,608, the drawings and disclosure of which are specifically incorporated herein by reference. Each of the probes disclosed in this patent reference includes a plurality of light sources that are mounted so that the light emitted thereby is transmitted to the tumor or other cells to be destroyed by PDT. The light sources used on the probes taught by this reference are preferably light emitting diodes (LEDs). By transcutaneously placing one of these probes at an internal treatment site and applying PDT for an extended time, abnormal tissue at the treatment site can be destroyed without adverse impact on surrounding normal tissue.

The design and shapes of probes disclosed in the above-referenced patent are not well suited for use in administering PDT for extended periods of time inside a patient's mouth. What is required is a method and apparatus that applies light of the desired waveband to a treatment site extending along a patient's gum line where undesirable organisms that cause oral disease principally reside. The application of light should ideally be provided by a source that can comfortably be left inside a patient's mouth for times ranging from, for example, thirty minutes to many hours. For example, it may be desirable to provide apparatus to administer

PDT that can be left inside a patient's mouth overnight, to minimize the affect of the treatment on the patient.

Summary of the Invention

In accord with the present invention, apparatus is provided for administering light therapy inside a patient's oral cavity. The apparatus includes a generally U-shaped fixture, sized to fit adjacent to a gum line of teeth, disposed inside the patient's oral cavity. A light source is coupled to the fixture and produces light having a predefined waveband. Means are also included for directing the light produced by the light source onto the gum line to administer the light therapy thereto.

The fixture preferably includes a groove that is seated over the teeth to administer the light therapy to the gum line. In one embodiment, the light source is coupled to the fixture by an optical fiber, and the means for directing the light comprise an end of the optical fiber that is disposed so that the end is adjacent to the gum line when the fixture is fitted to the teeth of the patient. Light emitted from the end of the optical fiber is then incident on the gum line. More specifically, the means for directing the light comprise a plurality of optical fibers that convey light from the light source, which is disposed outside of the patient's oral cavity, to a plurality of spaced-apart points disposed on the fixture at the gum line.

In another embodiment, the light source comprises a plurality of light emitting devices disposed in spaced-apart array on the fixture, so that said light emitting devices are substantially aligned with the gum line when the fixture is positioned in the patient's oral cavity. Optionally, the means for directing the light can comprise a diffusing material that diffuses light produced by the source, so that the light is incident more continuously along the gum line.

In each of the preferred embodiments, the means for directing the light are disposed along the two facing portions of the fixture so that the light is directed at the gum line along both an inner and an outer side of the teeth. The light source may comprise an LED, a laser diode, a vertical cavity surface emitting laser (VCSEL), a light emitting semiconductor, a gas discharge source, a light emitting polymer, or a filament bulb.

A further aspect of the present invention is directed to a method for applying a light therapy to treat disease in an oral cavity of a patient. The method includes steps that are generally consistent with the functions performed by the elements of the apparatus described above.

Brief Description of the Drawing Figures

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 is an isometric view of an fixture in accord with the present invention, for administering PDT to treat diseases of the oral cavity;

FIGURE 2 is an isometric view of the fixture of FIGURE 1, with hidden lines to show a recessed groove in the fixture that is adapted to fit over either the upper or lower teeth in a patient's mouth during administration of PDT;

FIGURE 3 is a plan view of the fixture shown in FIGURES 1 and 2;

FIGURE 4 is a cross-sectional view of the fixture, taken along section line 4-4 in FIGURE 3;

FIGURE 5 is a partial cut-away plan view of the fixture, showing the optical fibers that convey light to a plurality of spaced-apart points along an inner surface of the fixture;

FIGURE 5A is an enlarged portion of the fixture shown in FIGURE 5;

FIGURE 6 is a partial cut-away plan view of a second embodiment of the fixture, showing a plurality of light emitting devices positioned at points along an inner surface of the fixture;

FIGURE 6A is an enlarged portion of the fixture shown in FIGURE 6;

FIGURE 7 is a partial cut-away plan view of a third embodiment of the fixture, showing a plurality of light emitting devices mounted to a conductive strip that is embedded in a wall of the fixture;

FIGURE 7A is an enlarged portion of the fixture shown in FIGURE 7, showing an optional diffuser strip that is embedded in the inner wall of the fixture;

FIGURE 8 is a partial cut-away plan view of a fourth embodiment of the fixture, showing placement of an optical fiber used to convey light within the fixture; and

FIGURE 8A is an enlarged portion of the fixture shown in FIGURE 8, illustrating spaced-apart nicks in the cladding of the optical fiber that emit light directed toward the interior cavity of the fixture.

Description of the Preferred Embodiment

Several different embodiments of fixtures useful for administering PDT for extended periods of time inside a patient's mouth to destroy undesirable oral organisms are illustrated in the drawings. FIGURES 1 and 2 illustrate details of a

fixture 20 in accord with the present invention. Except as noted, fixture 20 is the same in each of the embodiments described below. The embodiments of the present invention differ primarily in the manner in which light is delivered to a treatment site extending along the gum line in a patient's mouth.

As shown in FIGURES 1 and 2, fixture 20 is generally U-shaped, appearing similar to a mouth guard of the type that is used for protecting teeth against bruxism or from injury during participation in sports activities such as football or boxing. An elastomeric biocompatible material such as a silicone or a soft polyurethane or other plastic is used to form fixture 20 into the desired shape. It is contemplated that a variety of sizes and shapes of fixture 20 may be made commercially available to accommodate the individual shape of a specific patient's oral cavity, since substantial variation exists in the dental configuration of teeth and gingival tissue among individuals within the general population.

As more clearly shown in FIGURE 2, fixture 20 includes an open trough or cavity 24 that is generally an inverted "U" shape in cross section and which has open ends 21, so that trough 24 in fixture 20 is seated over the teeth in a patient's mouth. Ideally, fixture 20 will be sized to fit the dental structure in a particular patient's oral cavity, and open ends 21 will be disposed adjacent the intramandible tissue, i.e., behind the point at which the patient's wisdom teeth are normally disposed. By providing the appropriate size fixture 20 fitted to a specific individual's mouth and dental structure, full exposure of the gum line on the lower and upper sets of teeth can be achieved.

While it is possible that two fixtures 20 may be used for simultaneously administering PDT to both the lower and upper sets of teeth within a patient's mouth, it will likely be more comfortable for the patient if the treatment is applied only to the upper or lower set of teeth at a time. In one preferred form of fixture 20, a lead 22 extends from the fixture to a point outside the patient's oral cavity. Depending upon the type of light source employed, lead 22 may convey an electrical current from an external power supply (not shown), such as a battery pack, that is fastened to the patient's clothing, or fixed behind the patient's ear (e.g., in the same manner as some hearing aids). Alternatively, as illustrated by the dashed line in FIGURE 1, instead of supplying electrical current to fixture 20 from an external power source, an internal battery 25, accessible by removing a cover 23 on the front of the fixture can be used to provide power to energize the light source contained within fixture 20. Internal battery 25 is less desirable, however, since it is likely to add to the bulk of fixture 20, and because the

materials used in batteries are potentially toxic, should any leakage occur from the internal battery that escapes past cover 23.

In FIGURE 3, a plan view of fixture 20 shows the position of a cross-sectional view taken along cross section lines 4-4. This cross-sectional view is illustrated in FIGURE 4. In the particular embodiment shown in FIGURE 4, fixture 20 includes a plurality of optical fibers in hexagonal shaped bundles 30a and 30b that are embedded within the structural body of the fixture, between an outer wall 26 and an inner wall 28. FIGURE 4 shows how the fixture is seated over the teeth of a patient, so that, for example, a molar 36 extends into trough 24 adjacent to and between facing inner walls 28 of the fixture. Bundles 30a and 30b are disposed at an elevation within fixture 20 so they are generally adjacent a gum line 38 in the patient's mouth when the fixture is seated on the patient's teeth.

As shown in FIGURES 5 and 5A, at spaced-apart intervals along inner walls 28 of the fixture, ends 34 of cleaved optical fibers 32 are deflected away from bundles 30a and 30b toward gum line 38. Light conveyed through optical fibers 32 from an external light source (not shown) is directed from ends 34 of the optical fibers onto gum line 38 to administer PDT that is intended to destroy undesirable disease-causing organisms at the gum line treatment site. Optical fibers in bundle 30a direct light onto the gum line on one side of molar 36, while optical fibers in bundle 30b direct light onto the gum line on the opposite side of molar 36. It will be apparent that bundle 30a is substantially larger and includes a greater number of optical fibers than bundle 30b, since fewer optical fibers remain in bundle 30b. The optical fibers comprising the bundles extend from fixture 20 through lead 22 to the external light source, e.g., to a low-powered laser or to one or more laser diodes. Alternatively, for exposures over even longer periods of time, light can also be supplied at a relatively lower intensity from lower power sources such as LEDs, VCSELs, or even filament bulbs. Light from one or more such sources is conveyed through lead 22 and distributed along the gum line by optical fibers 32, so that the entire gum line of the lower or upper set of teeth (both inner and outer sides) is exposed to the light to administer PDT.

As noted in the Background of the Invention above, PDT is preferably administered to a treatment site to which a photoreactive agent has already been applied; the photoreactive agent is preferentially absorbed by the organisms intended to be destroyed by the PDT. Any of the photoreactive agents that are described in the papers listed in the Background of the Invention or other photoreactive agents suitable for this purpose can be applied along the gum line of

the patient prior to insertion of the fixture in accord with the present invention, to effect PDT. Each type of photoreactive agent has a characteristic absorption waveband or range of wavelengths that are absorbed. Light having a corresponding waveband or range of wavelengths is then applied by fixture 20. Depending upon the concentration of the photoreactive agent, the type of organism intended to be destroyed, the intensity of the light at the treatment site, and various other parameters, which vary from individual to individual, fixture 20 may be left in place to provide the treatment for periods of time ranging from minutes to hours. After one set of teeth has been treated, the photoreactive agent can be applied along the gum line of the other set of teeth and the fixture applied to the other set of teeth to complete the therapy.

FIGURES 6 and 6A illustrate a second embodiment of the present invention that comprises a fixture 20' in which a plurality of LEDs, VCSELs, laser diodes, or other light emitting devices 52 are embedded within the walls of the fixture at spaced-apart intervals and oriented so that they emit light directed along the gum line of a patient. Fixture 20' is placed into a patient's mouth, with either the upper or lower set of teeth inserted into trough 24. Since the light emitting devices are embedded within the elastomeric material comprising the supporting body of fixture 20', the material preferably comprises an optically transparent polyurethane or other comparable plastic material. In addition, it is contemplated that the inner side of outer wall 26 can be made highly light reflective to improve the intensity of light applied to the gum line.

Electrical power to energize light emitting devices 52 is supplied through a lead 50 that extends from a lead 22', which is connected to an external power source. Alternatively, lead 50 may be connected to internal battery 25 (as indicated in FIGURE 1).

Yet another embodiment is represented by fixture 20" shown in FIGURES 7 and 7A. In this embodiment, a plurality of light emitting devices 62, including any of the various types of light sources noted above, are mounted on a substrate 60 that includes conductive traces 63a and 63b on its surface for conveying electrical current to energize the light emitting devices. Substrate 60 is sufficiently flexible to conform to a relatively small radius of curvature without damage, enabling it to curve around the radius of curvature of the fixture. Preferably, the surface of substrate 60 on which light emitting devices 62 are mounted is made highly light reflective to increase the intensity of light applied to

the gum light. In addition, the inner surface of outer wall 26 is also preferably highly light reflective, for the same purpose.

A pair of conductors 56 extends through external lead 22" and connects the external power supply to conductive traces 63a and 63b on substrate 60. Alternatively, as noted above, power may be supplied to the conductive traces from internal battery 25, which is located within the fixture.

In FIGURE 7A, a further optional detail is illustrated that is applicable to each of the embodiments of the present invention. Specifically, this drawing shows a diffuser 64 that is mounted within inner wall 28 of the fixture between the light emitting devices and the location of the gum line when the fixture is in use within a patient's mouth. Diffuser 64 has a relatively high index of refraction, at least along its linear axis, so that it disperses light emitted by the light emitting devices or by the optical fibers to provide a more even distribution of the light along the gum line. It is also contemplated that instead of diffuser 64, a simple linear lens assembly can be used for directing the light and dispersing it along the gum line of the patient.

The fourth embodiment of the present invention comprises a fixture 20'", as shown in FIGURES 8 and 8A. In this embodiment, an optical fiber 70 is disposed adjacent inner wall 28 at an elevation corresponding to the disposition of the patient's gum line when fixture 20'" is inserted over the teeth of the patient. Optical fiber 70 includes a cladding 72 that is applied to maximize internal reflections along the length of the optical fiber. However, at spaced-apart intervals, a plurality of nicks 82 are formed in cladding 72 on a side of the optical fiber directed toward inner wall 28. The material comprising the wall of fixture 20'" is optically transparent. At each point where a nick 82 is applied to the cladding along the length of the optical fiber, light escapes from inside the optical fiber to illuminate the gum line of the patient. Alternatively, cladding 72 can be textured (not shown) so that is has scratches, dimples, or grooves on its surface, or can include embedded particles, to facilitate light transmission through the cladding.

While not specifically shown as a separate drawing figure, it is also contemplated that an electroluminescent strip (generally appearing like optical fiber 70 in FIGURE 8) could also be used for producing light that is employed to administer PDT to the gum line of a patient. However, the light intensity of an electroluminescent strip is substantially lower than that emitted by the other types of light sources discussed above. Accordingly, it is likely that a substantially

longer period of treatment would be required to achieve the same beneficial results, i.e., the destruction of undesirable oral disease-causing organisms within the oral cavity. Other types of light sources are contemplated for use with this invention, including light emitting semiconductor materials and gas discharge light sources.

Although the present invention has been described in connection with several preferred forms, those of ordinary skill in the art will understand that many other modifications can be made thereto within the scope of the claims that follow. Accordingly, it is not intended that the scope of the invention in any way be limited by the above description, but instead be determined entirely by reference to the claims that follow.

The invention in which an exclusive right is claimed is defined by the following:

1. Apparatus for administering light therapy inside a patient's oral cavity, comprising:

(a) a substantially U-shaped fixture sized to fit adjacent a gum line of teeth disposed inside the patient's oral cavity;

(b) a light source coupled to the fixture, said light source producing light having a predefined waveband; and

(c) means for directing the light produced by the light source onto the gum line to administer the light therapy thereto.

2. The apparatus of Claim 1, wherein the fixture includes a groove that is seated over the teeth to administer the light therapy to the gum line.

3. The apparatus of Claim 1, wherein the light source is coupled to the fixture by an optical fiber, said means for directing the light comprising an end of said optical fiber disposed so that said end is adjacent to the gum line when the fixture is fitted to the teeth of the patient, light emitted from the end of the optical fiber being incident on the gum line.

4. The apparatus of Claim 1, wherein the light source comprises a plurality of light emitting devices disposed in spaced-apart array on the fixture, so that said light emitting devices are substantially aligned with the gum line when the fixture is positioned in the patient's oral cavity.

5. The apparatus of Claim 1, wherein the means for directing the light comprise a plurality of optical fibers that convey light from the light source outside of the patient's oral cavity, to a plurality of spaced-apart points disposed on the fixture.

6. The apparatus of Claim 1, wherein the means for directing the light comprise a diffusing material that diffuses light produced by the source, along the gum line.

7. The apparatus of Claim 1, wherein the means for directing the light are disposed along inner facing portions of the fixture so that the light is directed at the gum line along both an inner and an outer side of the teeth.

8. The apparatus of Claim 1, wherein the light source comprises one of a light emitting diode, a laser diode, a vertical cavity surface emitting laser, a light emitting polymer, a light emitting semiconductor, a gas discharge light source, and a filament bulb.

9. A fixture for administering photodynamic therapy within a patient's oral cavity, comprising:

(a) a supporting body having a generally U-shaped cross section, said supporting body being formed of a biocompatible material and being adapted to remain within the patient's oral cavity while administering the photodynamic therapy;

(b) a light source that emits light from the supporting body so that when the fixture is employed to administer the photodynamic therapy, light emitted by the light source is incident on a treatment site within the patient's oral cavity; and

(c) a lead coupled to the light source and adapted to connect to a power source, for supplying electrical power to energize the light source to administer the photodynamic therapy.

10. The fixture of Claim 9, wherein the light source comprises a plurality of light emitting devices that are spaced apart within the supporting body to emit light along an inner surface of the supporting body, said plurality of light emitting devices extending generally along a line aligned with a gum line in the patient's oral cavity when the fixture is being used to administer the photodynamic therapy.

11. The fixture of Claim 10, wherein the light emitting devices are coupled to a conductive trace that extends through the supporting body of the fixture.

12. The fixture of Claim 9, wherein the light source comprises an external light emitting device that is coupled to the supporting body through a plurality of optical fibers, said plurality of optical fibers terminating at spaced-apart points along an inner surface of the supporting body, so that when the fixture is employed to administer the photodynamic therapy to a gum line within the patient's oral cavity, light emitted by ends of the optical fibers is incident on the gum line.

13. The fixture of Claim 9, wherein the light source emits light within a predefined waveband.

14. The fixture of Claim 9, further comprising a diffuser supported by the supporting body of the fixture, for diffusing light emitted by the light source, thereby increasing an area over which the light is incident.

15. A method for applying a light therapy to treat disease in an oral cavity of a patient, comprising the steps of:

(a) providing a fixture adapted to fit within the oral cavity of the patient, said fixture being sized and shaped to be held adjacent teeth of the patient;

(b) producing light having a predefined waveband; and

(c) directing the light at a gum line of the patient to administer the light therapy to the patient.

16. The method of Claim 15, wherein the light therapy destroys organisms that cause gingival and periodontal diseases.

17. The method of Claim 15, further comprising the step of applying a photoreactive agent to the gum line, said photoreactive agent having a characteristic light absorption waveband that is substantially equal to the predefined waveband of the light directed at the gum line.

18. The method of Claim 15, wherein the step of directing the light comprises the step of diffusing the light to spread the light along the gum line.

19. The method of Claim 15, wherein the step of directing the light comprises the step of conveying the light into the oral cavity from an external source.

20. The method of Claim 19, wherein the light is conveyed by a plurality of optical fibers having ends disposed in a spaced-apart array along the gum line, so that the light emitted from the ends of the optical fibers is directed along the gum line.

21. The method of Claim 15, wherein the step of producing the light comprises the step of energizing a plurality of light emitting devices that are disposed in spaced-apart array adjacent to the gum line of the patient.

AMENDED CLAIMS

[received by the International Bureau on 7 November 1997 (07.11.97); original claims 1,4,6-11,13-18 and 21 amended and renumbered as claims 1 and 3-16; original claims 3,5,12,19 and 20 cancelled; new claims 17-20 added; remaining claim 2 unchanged (5 pages)]

The invention in which an exclusive right is claimed is defined by the following:

1. Apparatus for administering light therapy inside a patient's oral cavity, comprising:

(a) a substantially U-shaped fixture sized to fit adjacent a gum line of teeth disposed inside the patient's oral cavity;

(b) a plurality of light sources mounted on the fixture in a spaced-apart array, said light sources producing light having a predefined waveband that is substantially equal to a characteristic light absorption waveband of a photoreactive agent; and

(c) means for directing the light produced by the light sources onto tissue disposed along the gum line, so that light therapy can be administered to tissue that has absorbed the photoreactive agent.

2. The apparatus of Claim 1, wherein the fixture includes a groove that is seated over the teeth to administer the light therapy to the gum line.

3. The apparatus of Claim 1, wherein the plurality of light sources comprises a plurality of light emitting devices substantially aligned with the gum line when the fixture is positioned in the patient's oral cavity.

4. The apparatus of Claim 1, wherein the means for directing the light comprise a diffusing material that diffuses light produced by the plurality of light sources, along the gum line.

5. The apparatus of Claim 1, wherein the means for directing the light are disposed along inner facing portions of the fixture so that the light is directed at the gum line along both an inner and an outer side of the teeth.

6. The apparatus of Claim 1, wherein each of the plurality of light sources comprises one of a light emitting diode, a laser diode, a vertical cavity surface emitting laser, a light emitting polymer, a light emitting semiconductor, a gas discharge light source, and a filament bulb.

7. A fixture for administering photodynamic therapy within a patient's oral cavity, comprising:

(a) a supporting body having a generally U-shaped cross section, said supporting body being formed of a biocompatible material and being adapted to remain within the patient's oral cavity while administering the photodynamic therapy;

(b) a plurality of low intensity light sources that emits light having a predefined waveband, said plurality of low intensity light sources being mounted in the supporting body in a spaced-apart array, so that when the fixture is employed to administer the photodynamic therapy, light emitted by the light sources is incident on tissue at a treatment site within the patient's oral cavity, and the predefined waveband of the light is substantially equal to a characteristic light absorption waveband of a photoreactive agent that has been absorbed by said tissue; and

(c) a lead coupled to the light source and adapted to connect to a power source, for supplying electrical power to energize the light source to administer the photodynamic therapy.

8. The fixture of Claim 7, wherein the plurality of low intensity light sources comprises a plurality of light emitting devices that emit light along an inner surface of the supporting body, said plurality of light emitting devices extending generally along a line aligned with a gum line in the patient's oral cavity when the fixture is being used to administer the photodynamic therapy.

9. The fixture of Claim 8, wherein the light emitting devices are coupled to a conductive trace that extends through the supporting body of the fixture.

10. The fixture of Claim 7, wherein the plurality of low intensity light sources emits light within a predefined waveband.

11. The fixture of Claim 7, further comprising a diffuser supported by the supporting body of the fixture, for diffusing light emitted by the plurality of low intensity light sources, thereby increasing an area over which the light is incident.

12. A method for applying a light therapy to treat disease in an oral cavity of a patient, comprising the steps of:

(a) providing a fixture adapted to fit within the oral cavity of the patient, said fixture being sized and shaped to be held adjacent teeth of the patient;

(b) producing light from a plurality of sources disposed at spaced-apart points on the fixture, said light having a predefined waveband that is substantially equal to a characteristic light absorption waveband of a photoreactive agent;

(c) applying the photoreactive agent to tissue along a gum line of the patient diseased tissue and undesirable organisms disposed along the gum line preferentially absorbing the photoreactive agent; and

(d) directing the light produced by the plurality of sources at tissue along the gum line of the patient to administer the light therapy to the gum line in oral cavity of the patient, thereby destroying said diseased tissue and undesirable organisms.

13. The method of Claim 12, wherein the light therapy destroys organisms that cause gingival and periodontal diseases.

14. The method of Claim 12, further comprising the step of applying a photoreactive agent to the gum line, said photoreactive agent having a characteristic light absorption waveband that is substantially equal to the predefined waveband of the light directed at the gum line.

15. The method of Claim 12, wherein the step of directing the light comprises the step of diffusing the light to spread the light along the gum line.

16. The method of Claim 12, wherein the step of producing the light comprises the step of energizing a plurality of light emitting devices that are disposed adjacent to the gum line of the patient.

17. Apparatus for administering light therapy inside a patient's oral cavity, comprising:

(a) a generally U-shaped fixture sized to fit adjacent a gum line of teeth disposed inside the patient's oral cavity; and

(b) a solid state light source coupled to the fixture, said solid state light source producing light having a predefined waveband that is substantially equal to a characteristic light absorption waveband of a photoreactive agent applied to tissue at the gum line, said solid state light source being positioned to emit light directly onto a treatment site disposed along the gum line, so that light therapy can be administered to destroy diseased tissue and undesirable organisms that have preferentially absorbed the photoreactive agent.

18. Apparatus for administering light therapy inside an oral cavity of a patient, comprising:

(a) a substantially U-shaped fixture sized to fit adjacent a gum line of teeth disposed inside the oral cavity;

(b) a light source coupled to the fixture, said light source producing light having a predefined waveband that is substantially equal to a characteristic light absorption waveband of a photoreactive agent administered to the patient and absorbed by tissue along the gum line; and

(c) an inner reflective surface disposed in said fixture, said inner reflective surface reflecting the light produced by said light source onto the tissue disposed along the gum line with an enhanced intensity, so that light therapy can be administered to said tissue that has absorbed the photoreactive agent.

19. A fixture for administering a photodynamic therapy within a patient's oral cavity, comprising:

(a) a supporting body having a generally U-shaped cross section, said supporting body being formed of a biocompatible material and being adapted to remain within the patient's oral cavity while administering the photodynamic therapy, said body having an inner surface that is light reflective, said inner surface being disposed on the supporting body so that the inner surface faces towards tissue at a treatment site within the patient's oral cavity;

(b) a light source disposed on the supporting body, said light source emitting light having a predefined waveband appropriate to administer the photodynamic therapy, so that when inserted in the patient's oral cavity, light emitted by the light source is reflected by said inner surface onto tissue at the treatment site within the patient's oral cavity, thereby enhancing an intensity of light incident on the treatment site; and

(c) a lead coupled to the light source and adapted to connect to a power source, for supplying electrical power to energize the light source to administer the photodynamic therapy.

20. A method for applying a light therapy to treat disease in an oral cavity of a patient, comprising the steps of:

(a) providing a fixture adapted to fit within the oral cavity of the patient, said fixture being sized and shaped to be held adjacent teeth of the patient;

(b) producing light having a predefined waveband that is substantially equal to a characteristic light absorption waveband of a photoreactive agent;

(c) applying the photoreactive agent to tissue along a gum line of the patient diseased tissue and undesirable organisms disposed along the gum line preferentially absorbing the photoreactive agent; and

(d) reflecting the light at tissue along the gum line of the patient from an inner surface of said fixture that is light reflective, said inner surface being disposed along the gum line and adjacent to the diseased tissue and undesirable organisms, so that said diseased tissue and undesirable organisms are destroyed by the light therapy.

Fig. 1

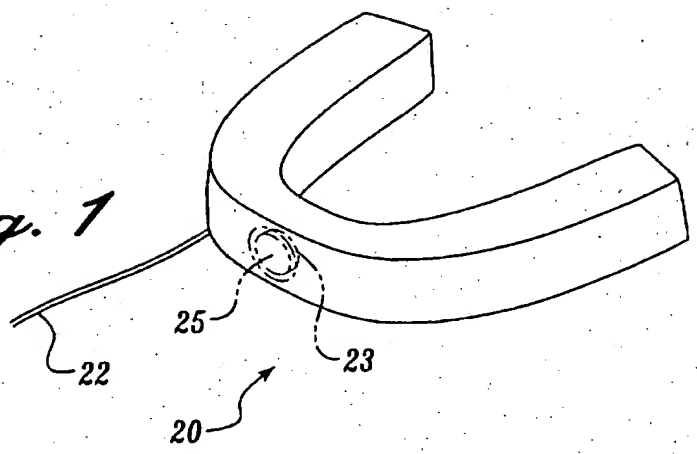
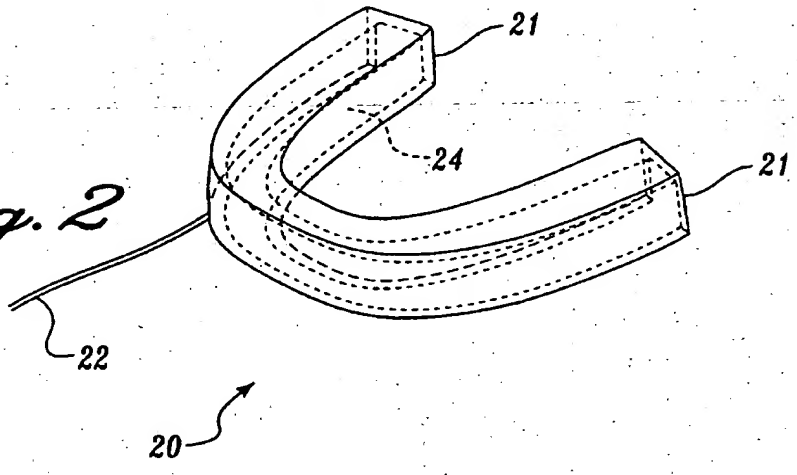


Fig. 2



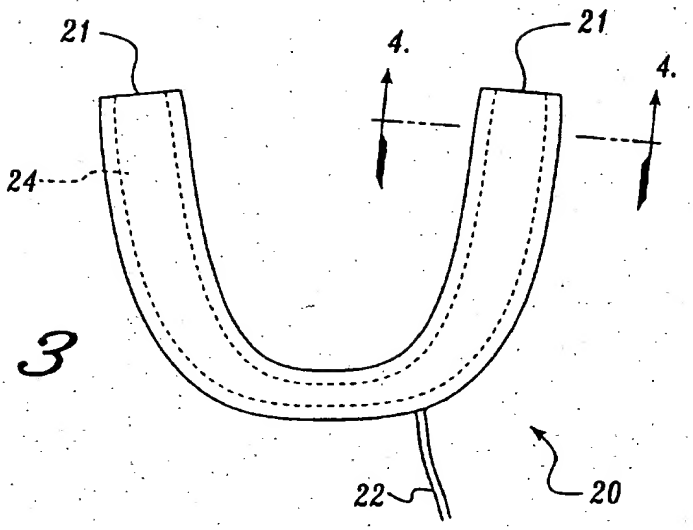


Fig. 3

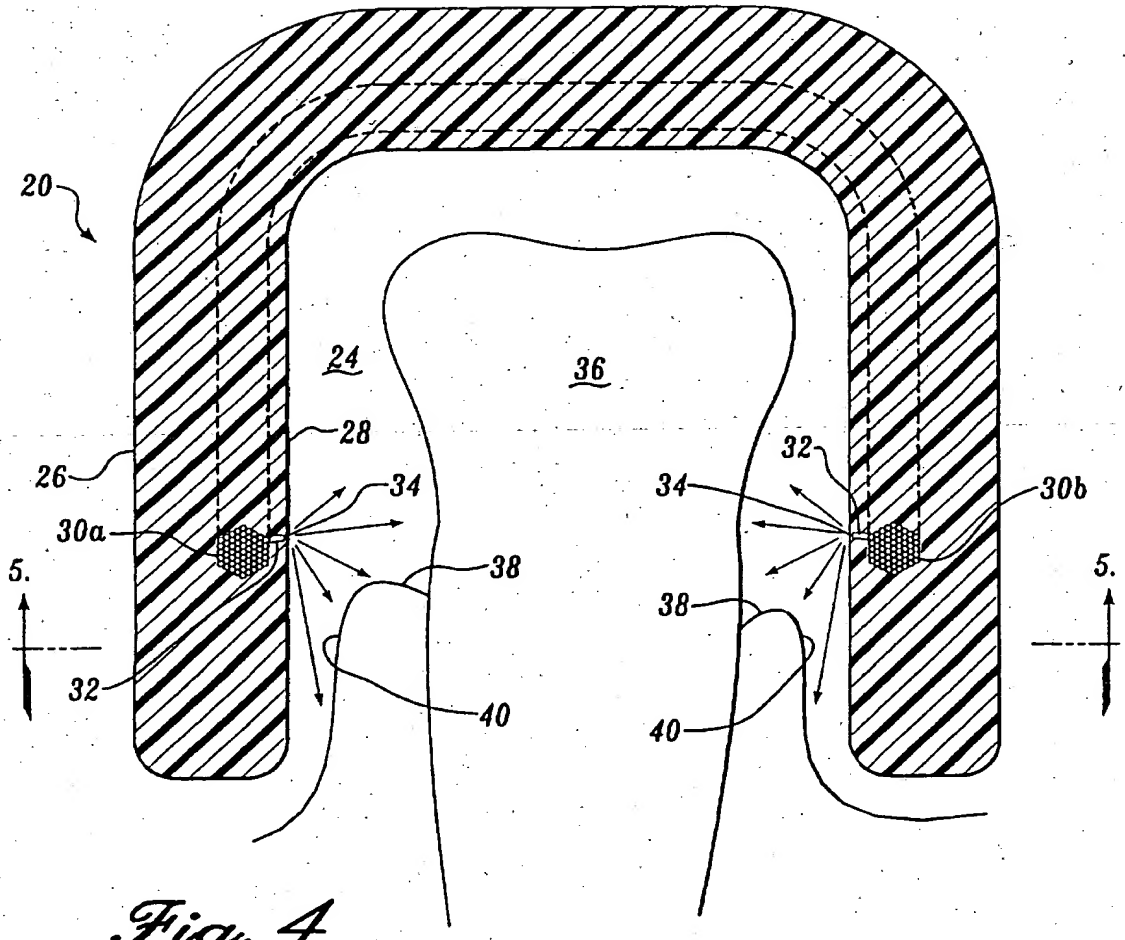


Fig. 4

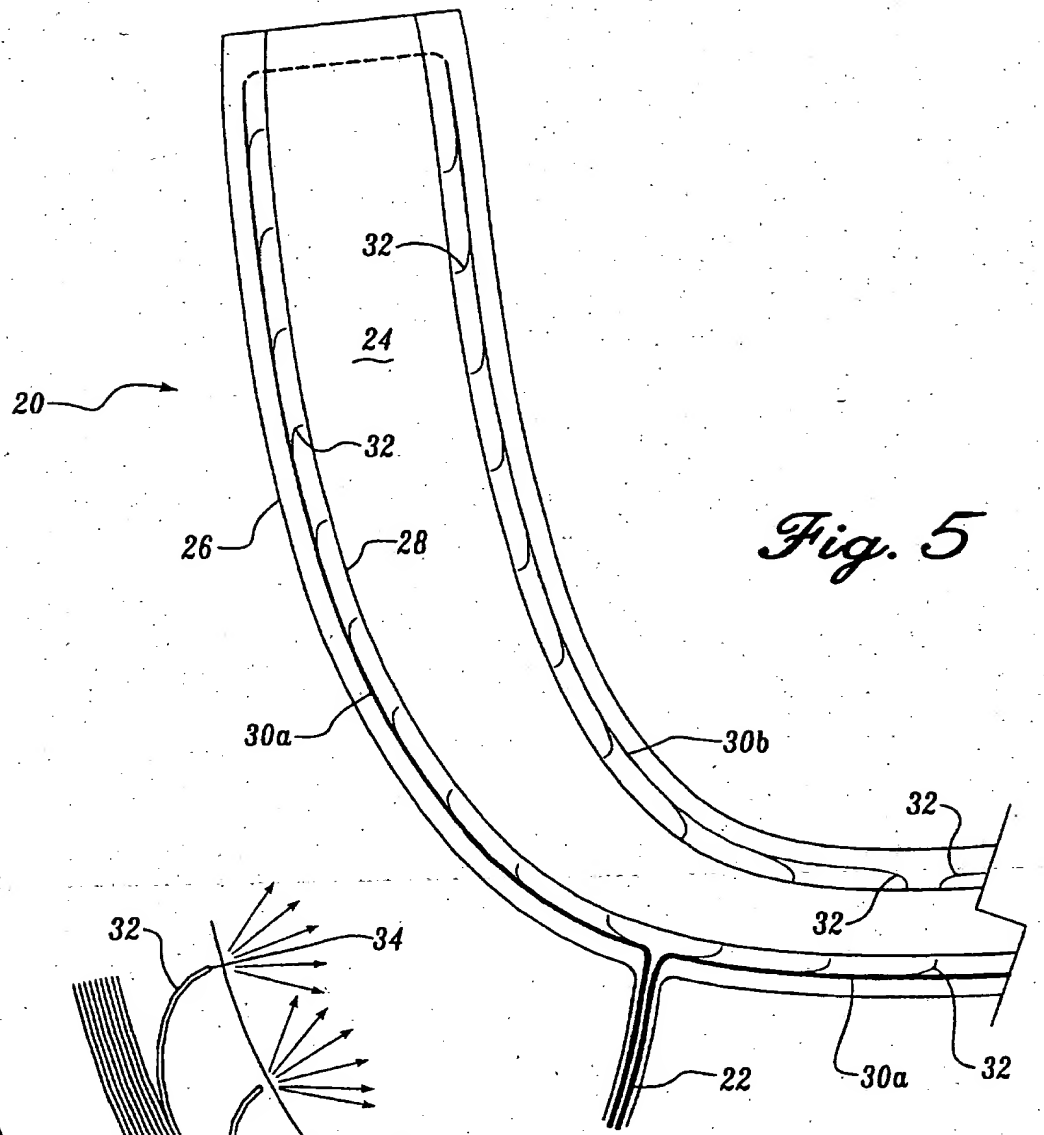


Fig. 5

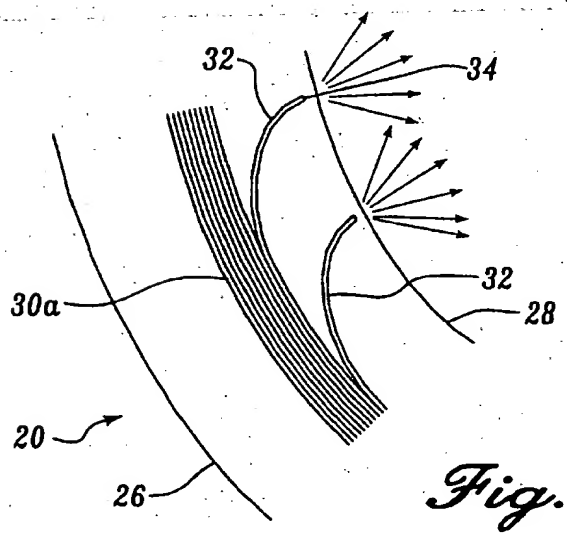


Fig. 5A

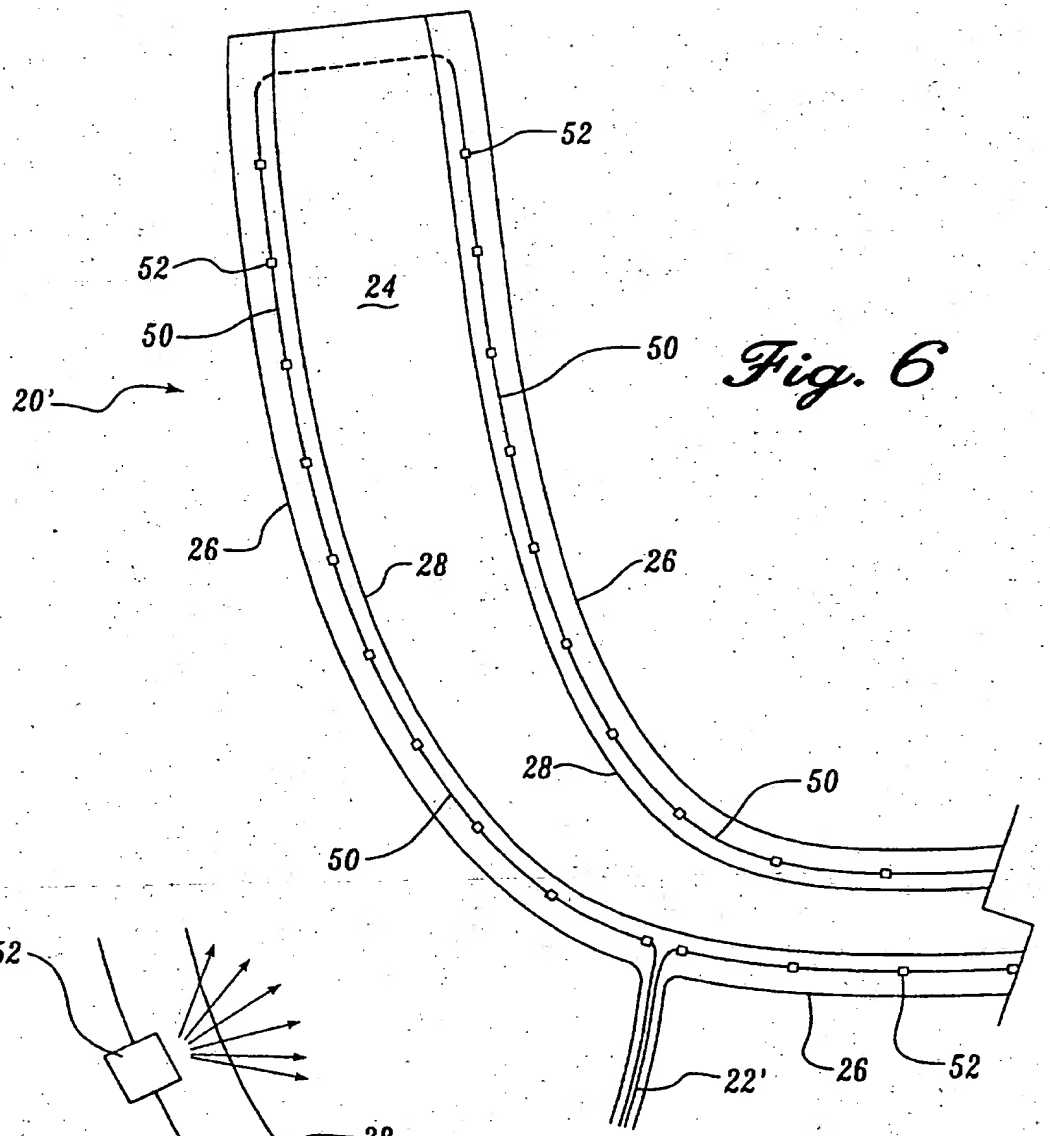


Fig. 6

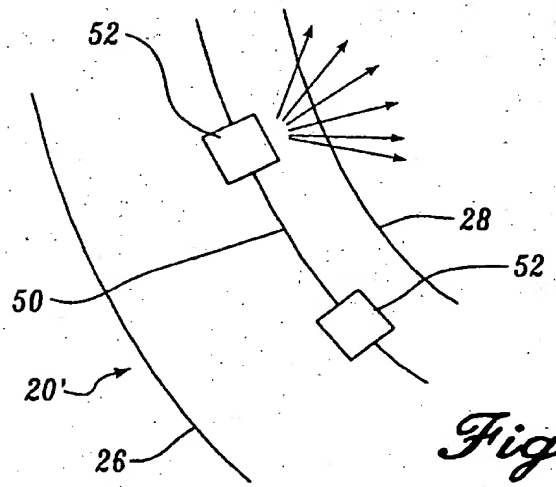


Fig. 6A

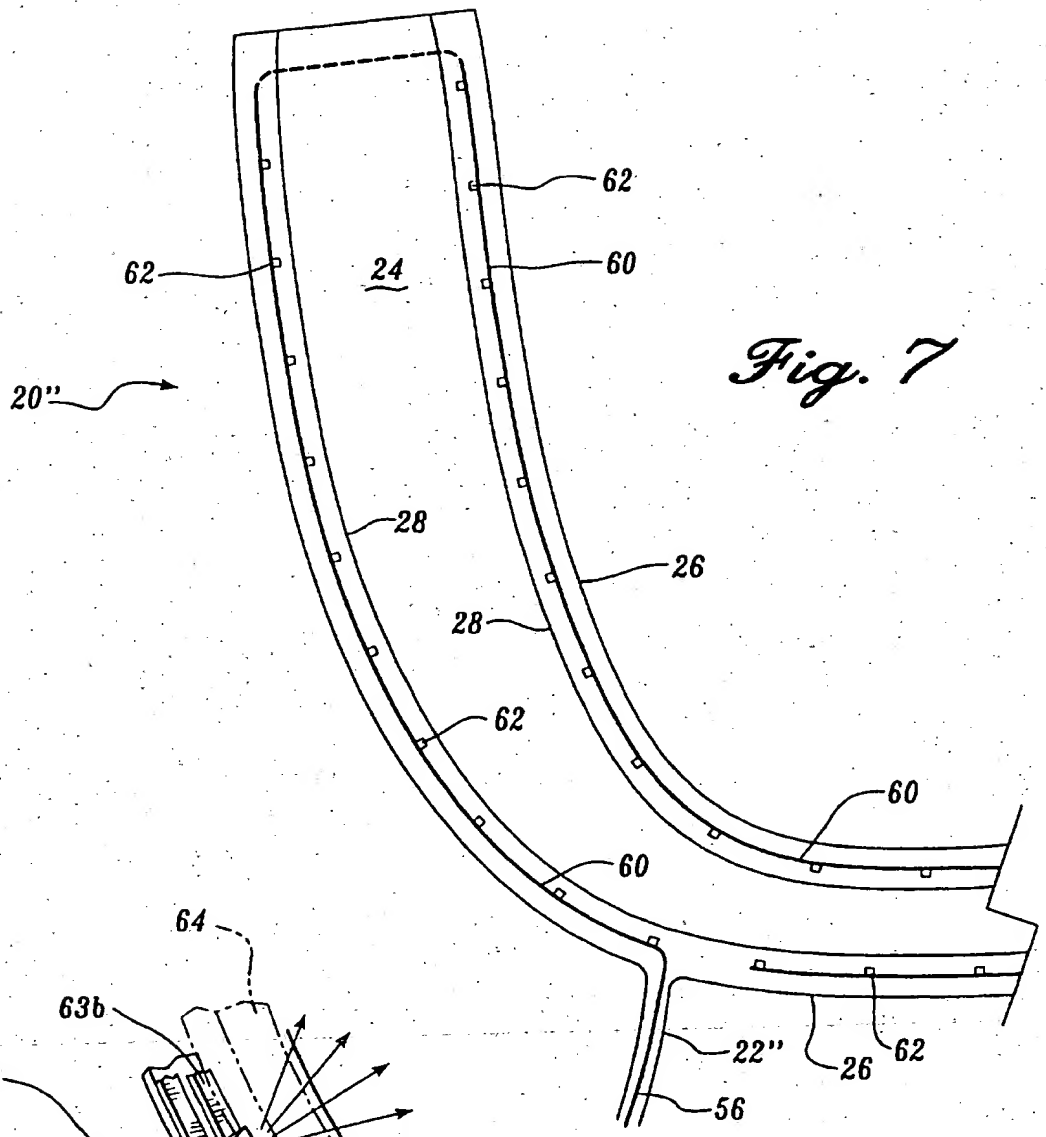


Fig. 7

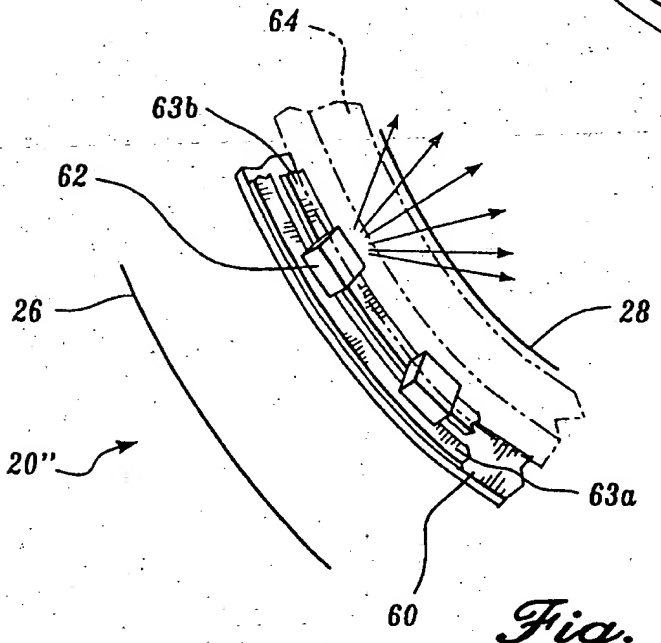


Fig. 7A

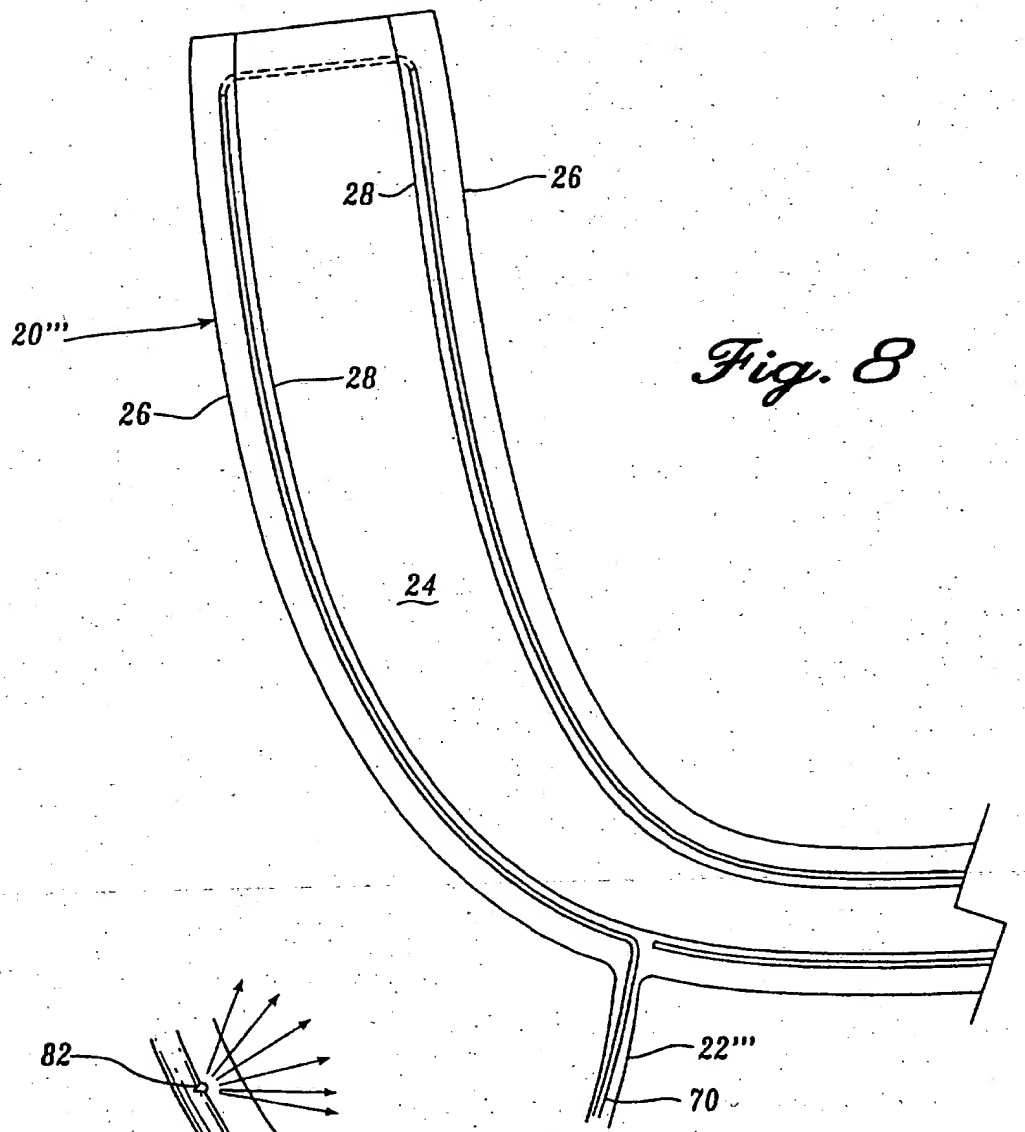


Fig. 8

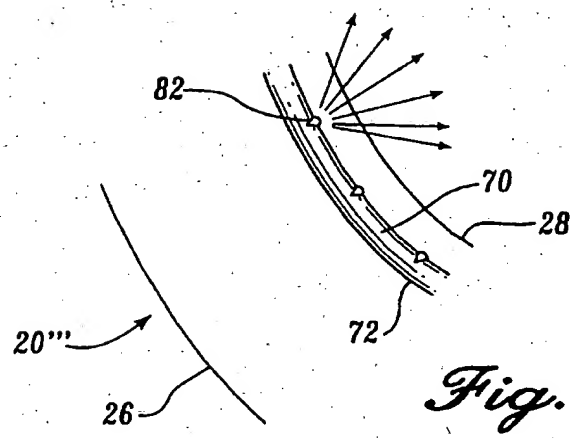


Fig. 8A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/11052

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 5/00
US CL :607/088

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/3, 9, 15; 607/088, 089, 092

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,339,810 A (IVERS et al) 23 August 1994, entire document.	1-21
X	US 4,852,549 A (MORI) 01 August 1989, entire document.	1-21

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 07 AUGUST 1997	Date of mailing of the international search report 03 SEP 1997
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Form PCT/ISA/210 (second sheet)(July 1992)*